

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

The Office Action Summary correctly indicates that claims 2-6, 15 17, 18 and 21-32 are pending in the application and stand rejected.

Claims 2-6, 15 17, 18 and 21-32 have been canceled without prejudice or disclaimer of the subject matter claimed therein, and without acceding to any ground of rejection that has been by the Office.

Claims 33-43 have been added. Claims 33-43 are derived from prior claims 4-5, 21-23 and the claims dependent thereon. Support for the new claims can be found throughout the specification and claims as originally filed, e.g. on pages 8-13 of the specification.

No prohibited new matter has been introduced by way of the above amendments. Applicants reserve the right to file a continuation or divisional application on subject matter canceled by way of this Amendment.

Current Rejections Rendered Moot

Claims 15, 17, 26, and 29-31 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Koderia (U.S. Patent No. 4,396,582).

Claims 15, 17, 26, and 29-31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Koderia (U.S. Patent No. 4,396,582) in view of Loliger et al (U.S. Patent No. 3,692,468).

Claims 18, 27, and 32 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Koderia (U.S. Patent No. 4,396,582) in view of Loliger et al (U.S. Patent

No. 3,692,468) as applied to claims 15, 27, 31, and further in view of Sizer et al. (U.S. Patent No. 5,843,374).

Claims 15, 26, and 30 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Koderia (U.S. Patent No. 4,396,582) in view of Bachmann et al. (U.S. Patent No. 4,175,140).

Claims 17, 18, 27, 31, and 32 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Koderia (U.S. Patent No. 4,396,582) in view of Bachmann et al. (U.S. Patent No. 4,175,140) as applied to claims 15, 26, 30, and further in view of Sizer et al. (U.S. Patent No. 5,843,374).

Claim 4 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ernstsson et al (U.S. Patent No. 3,884,012) in view of Sizer et al. (U.S. Patent No. 5,843,374) and further in view of Loliger et al. (U.S. Patent No. 3,692,468).

Claim 28 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ernstsson et al. (U.S. Patent No. 3,884,012) in view of Sizer et al. (5,843,374) and further in view of Loliger et al (U.S. Patent No. 3,692,468) and DiGeronimo (U.S. Patent No. 4,494,357).

Claims 5 and 25 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ernstsson et al. (U.S. Patent No. 3,884,012) in view of Sizer et al. (U.S. Patent No. 5,843,374) and further in view of DiGeronimo (U.S. Patent No. 4,494,357).

Claims 2, 3, 21, 23, and 24 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Ernstsson et al. (U.S. Patent No. 3,884,012) in view of Sizer et al. (U.S. Patent No. 5,843,374).

Claim 6 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ernstsson et al. (U.S. Patent No. 3,884,012) in view of Sizer et al. (U.S. Patent No.

5,843,374) as applied to claim 21 and further in view of Clark et al. (U.S. Patent No. 5,925,885).

Claim 22 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ernstsson et al. (U.S. Patent No. 3,884,012) in view of Sizer et al. (U.S. Patent No. 5,843,374).

Without acceding to any ground of rejection that has been by the Office, claims 2-6, 15 17, 18 and 21-32 have been canceled. Therefore these rejections have been rendered moot. The patentability of new claims 33-43 in view of the cited prior art is addressed below.

Patentability of claims 33-43

Below, the prior art that has been cited in the present Office Action is discussed with regard to new claims 33-43. Claims 33-43 are not anticipated by any of the cited prior art references. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

Each of claims 33-43 recites a method in which hydrogen peroxide solution having a concentration of 10% to 50% is applied to packaging material, a substantial amount of the hydrogen peroxide solution is then removed from the packaging sheet material, and the packaging sheet material is irradiated with UV light while it retains a trace amount of the hydrogen peroxide solution.

None of the prior art references that have been cited in the long history of this case disclosed or suggested the presently claimed method. At the time the invention was made,

the use of such a high concentration of hydrogen peroxide in combination with UV light was problematic because the effectiveness of the UV light was reduced at higher hydrogen peroxide concentrations. Hydrogen peroxide absorbs UV light, but water does not. So, the higher the concentration of hydrogen peroxide on a web, the less effective UV irradiation would become. The present inventors solved this and other problems by the presently claimed methods. The present inventors had the insight to understand that the prior art practice of leaving hydrogen peroxide solution on the surface of a web during irradiation resulted in shielding the microorganisms from a significant amount of the UV irradiation. Specification, at 5, lines 1-6. On the other hand, irradiating a dry web forgoes the synergistic effect of the hydrogen peroxide.

Surprisingly, the present inventor found that by removing all but trace amounts of hydrogen peroxide from the surface of the web, and irradiating the web containing only that trace amount, the synergistic effect is combining UV irradiation and hydrogen peroxide treatment is maintained while the shielding caused by hydrogen peroxide is minimized. This novel approach provides better results than are obtainable by the previously known methods. Specification at page 11, lines 3-25. Thus, the presently claimed method provides a significant advancement in the art that was not appreciated by the prior art.

Claims 33-43 are not anticipated by the cited references under 35 U.S.C. § 102

Kodera

U.S. Patent No. 4,396,582 (Kodera) discloses a method in which packaging material is subjected to both chemical and UV sterilization. However, Kodera does not teach the use of hydrogen peroxide. Kodera at col. 3, lines 22-24. Thus, Kodera cannot anticipate the present invention.

According to Koderá, the chemical and UV sterilization steps can be carried out simultaneously or sequentially. Koderá at col. 3, lines 12-21. The steps are preferably sequential. Koderá at col. 7, lines 35-39. A method where the steps are performed simultaneously clearly does not correspond to the present method and amounts to a teaching away from the innovations provided by the present methods.

On the other hand, when the chemical and UV sterilization steps are carried out sequentially according to the teaching of Koderá, the method does not permit leaving a trace or residual amount of chemical sterilant. Figure 5 illustrates an apparatus for carrying out the invention. Koderá at col. 9, lines 34-36. The apparatus includes a chemical bath 14 containing liquid sterilant 16. Koderá at col. 9, lines 42-45. Downstream from the sterilizing vessel 14, there is a set of air knives 82 followed by a dryer 88. Koderá at col. 10, lines 47-58. The air knife pair 82 functions to remove the liquid from both surfaces of the strip of packaging material P, and the dryer 88 to dry the strip subsequently.

Koderá unambiguously disclosed that where the chemical and UV steps are to be performed sequentially, the packaging material is dried after exposure to chemical sterilant and before irradiation with UV light. Thus, in addition to teaching against the combination of hydrogen peroxide and UV light. And certainly teaching against high concentration of hydrogen peroxide such as a concentration of 10% to 50%, Koderá did not disclose leaving a trace amount of hydrogen peroxide on the surface of the packaging material and irradiating the packaging material while the trace amount of hydrogen peroxide remains on the surface. Combination of Koderá with the remaining references is either contrary to the teachings of the references, or would not cure the deficiencies that have been pointed out above.

Ernstsson

U.S. Patent No. 3,884,012 (Ernstsson) discloses a method illustrated in Figures 1, 3 and 5 in which packaging material 2,3 passes through vats 8, 28 containing sterilizing liquid. Ernstsson at col. 4, lines 59-64. Behind the tanks are arranged elements 10,31 for the absorption of surplus liquid. Ernstsson also teaches that it is also possible to use an air knife (Fig. 1: 30) in place of elements 10,31 to cause excess liquid to return to the tank. Ernstsson at col. 4, line 64 to col. 5, line 5. Following the elements 10, 31, or 30 Ernstsson teaches the used of heating elements 16,32 so that residues of the treatment fluids evaporate. In all of the illustrated embodiments, the web is introduced into the sterile tunnel 1 after a drying operation. Ernstsson at col. 6, lines 31-34.

Thus, according to Ernstsson, the web is heat dried prior to reaching the sterilizing element 11, which is the only possible location of a UV light source. Ernstsson at col. 6, lines 57-62. Ernstsson teaches that “any residual traces of the treatment fluids are evaporated” prior to the packaging material entering the pre-treatment chamber that can include a UV light. Ernstsson at col. 7, lines 21-49.

The Office Action contended that Ernstsson teaches “applying a stream of air to the packaging sheet material (col. 5, lines 2-3 and figure 3:30) for removing a substantial amount of hydrogen peroxide while retaining a residual or trace quantity of hydrogen peroxide.” OFFICE ACTION, at 12. This contention is followed by the allegation that “Ernstsson teaches removing surplus hydrogen peroxide by providing air knives as explained in col. 5, lines 2-3 while hydrogen peroxide residues are left to be latter [sic] removed at an additional evaporation step.” *Id.*

This analysis presented in the Office Action ignores the fact that the combined effect of the air knife and the additional evaporation step are contrary to the requirement of the

present method that the web be irradiated while it retains a trace or residual amount of hydrogen peroxide. It must be noted that the further heat evaporation step (FIG. 3:32) occurs upstream of the UV irradiation element (FIG 3:11). Therefore, it is clear from the description of the Ernstsson method is that the web is dried such that all hydrogen peroxide residues are removed prior to UV irradiation. Ernstsson does not teach or suggest irradiating the web while it retains a trace amount of hydrogen peroxide.

Ernstsson did not disclose the use of hydrogen peroxide at the recited concentrations, or steps of leaving a trace amount of hydrogen peroxide on the surface of the packaging material and irradiating the packaging material while the trace amount of hydrogen peroxide remains on the surface. Thus, Ernstsson cannot cure the deficiencies of Kodera.

Sizer

U.S. Patent No. 5,843,374 (Sizer) is directed to an apparatus and method for sterilizing packaging material through irradiation with a UV lamp subsequent to subjecting the packaging material to hydrogen peroxide. Sizer at col. 1, lines 7-12. According to the method taught by Sizer, a sterilant liquid is applied to the interior surface of packaging material and the material is then irradiated with UV light. The liquid sterilant is removed only after UV irradiation. Sizer at col. 4, lines 33-35; see also col. 6, line 61 to col. 7, line 4.

Thus, Sizer does not disclose removing a substantial amount of hydrogen peroxide from packaging sheet material to which hydrogen peroxide has been applied until only a trace amount of the hydrogen peroxide remains on the packaging sheet material and then irradiating the surface of the packaging sheet material with UV light while said packaging material still retains a trace quantity of hydrogen peroxide. Indeed, Sizer must be considered to teach against the present method as a whole.

DiGeronimo

U.S. Patent No. 4,494,357 (DiGeronimo) discloses the combination of sonication and UV light for sterilizing packaging material. FIG. 2 illustrates how the method can be applied to a continuous process for sterilization of web material. DiGeronimo at col. 5, lines 37-42. Web material 32 passes through liquid bath 34 and “would then be dried by means of air knives 40” or other means. DiGeronimo at col. 5, lines 45-58. After passing up and out of the liquid bath 34 and dried by air knives 40, the moving web 32 passes near a source of UV light 42. DiGeronimo at col. 5, lines 60-64.

Thus DiGeronimo discloses a method in which web material is dried between a sonication bath sterilization step and a UV sterilization step. DiGeronimo did not disclose irradiating the packaging material while a trace or residual amount of hydrogen peroxide remains on the surface.

Loliger

U.S. Patent No. 3,692,468 (Loliger) discloses the use of a hydrogen peroxide bath to sterilize packaging material. Loliger does not teach the use of UV irradiation. Thus, Loliger cannot be considered to teach a person of ordinary skill anything regarding the appropriate concentration of hydrogen peroxide in a method utilizing UV radiation, or how to solve the problem of UV shielding by hydrogen peroxide without losing the benefit of synergy that the present inventors have solved.

Clark

U.S. Patent No. 5,925,885 (Clark) discloses the use of short high-intensity pulses of polychromatic light for the deactivation of microorganisms. Clark does not disclose applying and removing hydrogen peroxide while leaving a trace amount of hydrogen peroxide on the surface of the packaging material and irradiating the packaging material while the trace

amount of hydrogen peroxide remains on the surface. Thus, Clark cannot be considered to teach a person of ordinary skill in the art how to solve the problem of achieving synergy between hydrogen peroxide killing and UV irradiation killing without the losses in efficiency caused by hydrogen peroxide shielding of microorganisms from UV radiation.

Patentability of claims 33-43 under 35 U.S.C. § 103

As shown above, none of the references discloses the method of the claimed invention. Furthermore, the references would not have rendered the invention obvious within the meaning of 35 U.S.C. § 103.

Before a reference or references can be used to reject a claim under 35 U.S.C. § 103, a *prima facie* case of obviousness must be established. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. M.P.E.P. § 2143.

As discussed above, the prior art taught either irradiating packaging material while wet or completely drying the packaging material entirely prior to irradiation. None of the references taught or suggested how to solve the problem of UV shielding by concentrations of hydrogen peroxide in the 10% to 50% range while retaining the synergistic effect provided by the combination at the same time.

None of the prior art references suggested the solution to this problem that was discovered by the present inventor, the claimed method of combining the use of hydrogen peroxide at the high concentrations recited in the claims and then substantially removing hydrogen peroxide so that only a trace amount of hydrogen peroxide remained on the

packaging sheet material, and while the packaging material still retained said trace quantity of hydrogen peroxide, irradiating the surface of the packaging sheet material with UV light.

An analysis of obviousness of a claimed combination must include consideration of the results achieved by that combination. *The Gillette Co. v. S.C. Johnson & Son Inc.*, 16 USPQ2d 1923, 1928 (Fed. Cir. 1990). Critical to the analysis is an understanding of the particular results achieved by the new combination. *Id.* (citing *Interconnect Planning Corporation v. Feil*, 227 U.S.P.Q. 543, 551 (Fed. Cir 1985)). The present inventor had the insight to understand that by performing the sterilization in the manner now claimed, the synergistic effects of combining hydrogen peroxide treatment with UV irradiation could be optimized while avoiding UV shielding and other problems inherent in processing wet material in a high-speed filling machine. None of the references that taught a step of drying the web between wetting with sterilant and UV irradiation contemplated retaining a synergistic effect. That is because a person of ordinary skill would have considered that by drying the web, the method was forgoing any synergistic effect.

There is no evidence in the prior art of any reason why a person of ordinary skill would have contemplated wetting web with 10% to 50% hydrogen peroxide, then removing all but a trace amount of hydrogen peroxide prior to UV irradiation. Consequently, there can be no basis for making a prima facie case against claims 33-43.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

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